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Application No.: 10/600,990
Reply to Final Office Action of Dec 01, 2006

Patent
Attorney Docket No.: CU-3263

I. REMARKS / ARGUMENTS

A. Summary of Amendments

The Application now contains 35 claims.

Claims 1-48 remain cancelled.

Claims 66-76 have been newly cancelled without prejudice. In light of the finality of this action, these claims were cancelled in order to move the present application forward. The Applicant reserves the right to pursue protection for these claims at a later date.

Claims 49-65 and 77-85 remain the same.

Claims 86-94 have been newly added. No new matter has been added to the present application under the current amendment.

B. Summary of Rejection under 35 USC §112 and Response

On page 2 of the Office Action, the Examiner indicates that claims 62-65 and 76 fail to comply with the written description requirement and are thus rejected under 35 USC §112. Specifically, the Examiner indicates that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention.

With regard to claim 76, the Applicant respectfully submits that this claim has been cancelled from the present application without prejudice, and that as such the Examiner's rejection to this claim is rendered moot.

With regard to claims 62-65, the Applicant respectfully disagrees with the Examiner, and submits that support for these claims can be found in the application as originally filed. More specifically, support for claims 62-65, which refer to the health characteristic,

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the certain outcome and the database being a first health characteristic, a first certain outcome and a first database. The process of claims 62-65 then describes providing a second health characteristic associated with a second certain outcome and accessing a second database.

The Applicant respectfully submits that support for providing more than one health characteristic can be found in the description at page 7, lines 15-23 and page 8, lines 10-21; Given that each measurement is associated with a certain outcome, if more than one health characteristic is provided, it follows that each one could be associated with a respective health characteristic. Furthermore, different databases and tables are disclosed on page 12, line 12 to page 14, line 25; and page 16, lines 1-32, which would thus have conveyed to one skilled in the relevant art that the inventors had possession of the concept of being able to access multiple databases based on different health characteristics that are provided.

In the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), it is established that in order to satisfy the enablement requirement of 35 U.S.C. §112, paragraph 1, the specification must enable one of ordinary skill in the art to practice the claimed invention without undue experimentation. Given that the specification provides a description of providing more than one health characteristic, and provides a clear description of the manner in which a database is accessed, the Applicant respectfully submits that a person of reasonable skill in the art would be able to access a second database, in the manner outlined in claim 62 without undue experimentation.

Accordingly, when considering the requirement for enablement set out in *In re Wands* it is clear that the present application satisfies the requirement for enablement. In light of this, the Applicant respectfully submits that there is both support and enablement for claims 62-65 in the present application. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. §112.

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C. Summary of Rejection under 35 USC §102 and Response

On page 3 of the Office Action, the Examiner has rejected claims 49-53, 56, 62-69, 72-78, 81 and 85 under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,609,156 (hereinafter referred to as Keith et al.).

With regards to claims 66-69 and 72-76, the Applicant respectfully submits that these claims have been cancelled from the present application without prejudice, such that the Examiner's rejection to these claims is rendered moot.

With regards to claims 49-53, 56, 62-65, 77-78, 81 and 85, the Applicant respectfully submits that the subject matter of these claims patentably distinguishes over the cited prior art, as discussed below.

Claims 49-53, 56, 62-65

For ease of reference, independent claim 49 has been reproduced herein below:

Claim 49

A process for monitoring an obstetrics patient, said process comprising:

- a) providing a user interface control operable by a user, the user interface control allowing the user to input information on a status of a health characteristic of the obstetrics patient, the status of the health characteristic being associated with a probability of a certain outcome;
- b) **accessing a database in response to the user inputting information on the status of the health characteristic via the user interface control, the database mapping either one of different possible statuses of the health characteristic or different possible probabilities of the certain outcome to respective actions for causing a change in the probability of the certain outcome;**
- c) identifying in the database a particular action *for causing a change in the probability of the certain outcome* at least in part on a basis of the information input by the user;
- d) conveying data indicative of the particular action to the user via a display.

The Applicant respectfully submits that the reference cited by the Examiner does not disclose, teach or suggest the above-emphasized limitation of independent claim 49. More specifically, nowhere does Keith et al. disclose a process for monitoring an obstetrics patient that involves "accessing a database *in response to the user inputting information* on the status of the health characteristic via the user interface control, *the database mapping either one of different possible statuses of the health characteristic*

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or different possible probabilities of the certain outcome to respective actions for causing a change in the probability of the certain outcome".

In order to fully appreciate the differences between the system described by Keith et al. and the invention set forth in independent claim 49, it is important to first have a clear understanding of the medical signal analyzer described by Keith et al. As described in col 3, lines 62-65 of this reference, the signal analyzer receives signals from foetal scalp sensors and uterine pressure sensors. These signals are then digitized and processed (via interpretation rules) in order to extract and classify features of the data. The features include accelerations and decelerations associated to a foetal heart rate. The extracted features, together with information specific to a pregnancy, represent short-term knowledge. This short-term knowledge is then processed by an expert system comprising an inference engine and long term medical knowledge, in order to provide an interpretation of the condition of the foetus. More specifically, the inference engine of the expert system applies a forward and backward chaining strategy to the short-term and long-term knowledge (neither of which is user entered) in order to assess a level of concern for a foetus. In essence, Keith et al. simply provides a mechanism for interpreting information in the foetal heart rate signal to determine whether the foetus is in a critical state.

Nowhere does Keith et al. disclose a "user interface control allowing the user to input information on a status of a health characteristic of the obstetrics patient" and "accessing a database in response to the user inputting information on the status of the health characteristic" wherein the database maps either *that health characteristic* or different possible probabilities of the certain outcome to respective actions. Instead, in Keith et al. an inference engine applies a forward and backward chaining strategy to short-term and long-term knowledge, neither of which is user entered. In order to assess the level of concern for a foetus. Rather, this processing is performed on the foetal heart rate signal provided through a foetal heart rate monitor.

The only place where Keith et al. remotely suggests that information can be entered by a user is in column 8, lines 32-35, which states that "the inference engine *may* forward

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chain with information previously established...or information obtained interactively with the midwife (the administration of drugs, FBS results, progress of the labour, etc.". Firstly, the Applicant respectfully submits that nowhere is it indicated that in response to midwife entered information a database is accessed. Instead, the information entered by a midwife is used to lead to a position in a knowledge tree using the forward and backward chaining strategy. Secondly, the Applicant respectfully submits that nowhere is it described that a database maps the midwife entered information, or a probability of a certain outcome associated with the midwife entered information, to an action for causing a change in the probability of the certain outcome. Instead, the only database discussed by Keith et al. is a database 10 that contains long term medical knowledge that has been constructed using many production rules. This database in no way simply maps the midwife-entered information to an action. Therefore, not only does Keith not describe that a database is accessed in response to the user inputting information, Keith et al. also does not describe that user entered information is mapped to an action for causing a change in the probability of the certain outcome. As such, the above limitations of independent claim 49 are clearly absent from Keith et al.

The Applicant further submits that Keith et al. discloses a complex medical signal analyzer for managing labour. As has been stated in previous Office Action responses, the complexity of prior art systems, including that of Keith et al., teaches away from the simplicity of the invention set forth in independent claim 49. In Keith et al., health characteristic data obtained from the sensors undergoes many complex processes, such as conversion into histograms, application of interpretation rules to the histograms, feature extraction in order to generate short term knowledge and then processing of that short term knowledge via an expert system that applies many production rules in order to interpret the condition of the fetus. As indicated in Column 3, lines 56-59, of Keith et al. "an intelligent, automatic analysis assessment of the vast amount of information available before and during labour is required" in order to adequately manage labour. This lengthy, and complex process is clearly in contrast to, and precludes, the straight-forward steps of the claimed invention, which recite (1) *accessing a database in response to the user inputting information on the status of the health characteristic*, wherein this database maps either one of different possible

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statuses of the health characteristic or different possible probabilities of a certain outcome to respective actions for causing a change in the probability of the certain outcome and (2) identifying in the database a particular action... at least in part on a basis of the information input by the user.

In light of the above, the Applicant respectfully submits that Keith et al. does not disclose all the limitations of independent claim 49. As per §2131 of the MPEP, in order "to anticipate a claim, the reference must teach every element of the claim". Since Keith et al. does not teach the above-emphasised limitations of independent claim 49, the Applicant respectfully submits that this reference is insufficient to support a rejection based on anticipation. Accordingly, independent claim 49 is believed to be in allowable form over the reference cited, and the Examiner is respectfully requested to withdraw the rejection to independent claim 49.

Claims 50-65 depend from independent claim 49, and as such incorporate by reference all of the limitations contained therein, including those already shown to be absent from Keith et al. Accordingly, dependent claims 50-65 are also believed to be novel and non-obvious over the cited prior art. Accordingly, the Examiner is respectfully requested to withdraw the rejection to dependent claims 50-65.

Claims 77-85

For ease of reference, independent claim 77 has been reproduced herein below:

Claim 77

A process for monitoring an obstetrics patient, said process comprising:

- a) providing a user interface control operable by a user, the user interface control allowing the user to input information on health characteristics of the obstetrics patient;
- b) receiving from the user via the user interface control a measurement of a particular health characteristic of the obstetrics patient, the particular health characteristic being modifiable, the measurement of the particular health characteristic being associated with a likelihood of a certain outcome;
- c) processing the measurement received from the user to determine an action for causing the particular health characteristic to be modified such as to cause a change in the likelihood of the certain outcome;
- d) conveying data indicative of the determined action to the user via a display.

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The Applicant respectfully submits that the reference cited by the Examiner does not disclose, teach or suggest the above-emphasized limitation of independent claim 77. More specifically, nowhere does Keith et al. disclose a process for monitoring an obstetrics patient that involves "receiving from the user via the user interface control a measurement of a particular health characteristic of the obstetrics patient, *the particular health characteristic being modifiable*" and "processing the measurement received from the user to determine an action for causing the particular health characteristic to be modified".

The medical signal analyzer described by Keith et al. operates mainly on signals received from sensors (such as foetal scalp sensors and uterine pressure sensors). As described in col. 8, lines 33-37, any data input by a user (such as a midwife) to the system is secondary and may only be required in certain cases. There is certainly no teaching or even suggestion in Keith et al. that the medical characteristics entered by a user (i.e. the administration of drugs, FBS results, progress of the labour) are processed in order to determine *an appropriate action for causing the particular health characteristic to be modified*. Instead, Keith et al. simply indicates, in very general terms, that the system is able to establish a level of concern for foetal well being, and suggest an appropriate course of action. Figure 13 provides more insight into the type of action that Keith et al. teaches, which appears to be simply an indication as to when to initiate delivery of the baby. Nowhere does Keith et al. specifically describe receiving from a user a measurement of a modifiable health characteristic, and processing that characteristic received from a to determine an action for causing the particular health characteristic to be modified.

In light of the above, the Applicant respectfully submits that Keith et al. does not disclose all the limitations of independent claim 77, and that as such this reference is insufficient to support a rejection based on anticipation, as per §2131 of the MPEP. Accordingly, independent claim 77 is believed to be in allowable form over the reference cited, and the Examiner is respectfully requested to withdraw the rejection to independent claim 77.

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The Applicant further submits that Keith et al. does not disclose the limitations of dependent claims 81-82, which indicate that the measurement of the health characteristic can be a measurement of a uterine cervix, and specifically a measurement of the ripeness of the uterine cervix. In addition, Keith et al. does not disclose the limitation of dependent claim 83, which indicates that an action for causing the health characteristic to be modified is a treatment for affecting the ripeness of the cervix. By modifying the measurement of the ripeness of the uterine cervix, the likelihood of a delivery by caesarean section can be altered.

The Applicant respectfully submits that none of these limitations is taught by Keith et al. Moreover, given that Keith et al. discloses a foetal heart rate monitor, it follows that Keith et al. does not disclose entering measurements associated to a health characteristic of a of a pregnant woman about to give birth, such as a measurement of a uterine cervix. Furthermore, Keith et al. does not disclose providing a suggested action for causing the ripeness of the uterine cervix to be modified, which in turn causes the likelihood of the certain outcome, namely a delivery by caesarean section, to be modified.

Claims 78-85 depend from independent claim 77, and therefore incorporate by reference all of the limitations contained therein, including those features already shown above to be absent from Keith et al. The Applicant further submits that many of the limitations contained in dependent claims 78-85 are on their own, novel and non-obvious over Keith et al. Accordingly, dependent claims 78-85 are also believed to be novel and non-obvious over the cited prior art and, as such, in condition for allowance.

D. Summary of Rejection under 35 USC §103 and Response

On page 4 of the Office Action, the Examiner has rejected claims 54, 55, 70, 71, 79 and 80 under 35 USC §103(a) as being unpatentable over Keith et al. in view of U.S. Patent No. 6,470,320 (hereinafter referred to as Hildebrand et al.).

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With regard to claims 70 and 71, the Applicant respectfully submits that these claims have been cancelled from the present application, thus rendering the Examiner's rejection to these claims moot.

With regard to claims 54 and 55, the Applicant respectfully submits that these claims depend from independent claim 49, and thus incorporate by reference the following limitation which has already been found to be absent from Keith et al. The Applicant further submits that this limitation is also absent from Hildebrand et al.

accessing a database in response to the user inputting information on the status of the health characteristic via the user interface control, the database mapping either one of different possible statuses of the health characteristic or different possible probabilities of the certain outcome to respective actions for causing a change in the probability of the certain outcome

Hildebrand et al. relates to a method for improving the delivery of health care to patients. Multimedia data signals are entered into the system along with clinical data relating to a patient, and on the basis of this information a recommendation is generated as to whether the patient would benefit from immediate patient care. Nowhere does Hildebrand et al. disclose enabling a user to enter health characteristic data via a user interface control, or "accessing a database in response to the user inputting information" wherein the database maps "the health characteristic or different possible probabilities of the certain outcome to respective actions for causing a change in the probability of the certain outcome". Accordingly, Hildebrand et al. does not disclose the above emphasized limitation of independent claim 49.

In accordance with §2142 of the MPEP, in order to establish a *prima facie* case of obviousness, the combination of references cited by the Examiner must teach all the limitations found in the claim. Since neither Keith et al. nor Hildebrand et al. disclose the above emphasized limitation of independent claim 49, and since claims 54 and 55 both incorporate by reference this limitation, the Applicant respectfully submits that this combination of references is insufficient to establish a rejection based on *prima facie* obviousness. Accordingly, claims 54 and 55 are believed to be in condition for allowance over the references cited, and the Examiner is respectfully requested to withdraw the rejection to dependent claim 54 and 55.

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With regard to claims 79 and 80, the Applicant respectfully submits that these claims depend from independent claim 77, and thus incorporate by reference the following limitations which have already been found to be absent from Keith et al. The Applicant further submits that these limitations are also absent from Hildebrand et al.

- e) receiving from the user via the user interface control a measurement of a particular health characteristic of the obstetrics patient, the particular health characteristic being modifiable, the measurement of the particular health characteristic being associated with a likelihood of a certain outcome;
- f) processing the measurement received from the user to determine an action for causing the particular health characteristic to be modified such as to cause a change in the likelihood of the certain outcome;

For the same reasons as those presented above with respect to independent claim 49, the Applicant respectfully submits that Hildebrand et al. does not disclose "receiving from the user via the user interface control a measurement of a particular health characteristic of the obstetrics patient". It thus follows that Hildebrand et al. does not disclose that this particular health characteristic is modifiable. The Applicant further submits that nowhere does Hildebrand et al. disclose "processing the measurement received from the user to determine an action for causing the particular health characteristic to be modified". Accordingly, Hildebrand et al. does not disclose the above emphasized limitation of Independent claim 77.

Since neither Keith et al. nor Hildebrand et al. disclose the above emphasized limitation of independent claim 77, and since claims 79 and 80 both incorporate by reference this limitation, the Applicant respectfully submits that this combination of references is insufficient to establish a rejection based on *prima facie* obviousness. Accordingly, claims 79 and 80 are believed to be in condition for allowance over the references cited, and the Examiner is respectfully requested to withdraw the rejection to dependent claim 79 and 80.

On page 5 of the Office Action, the Examiner has rejected claims 57, 58, 82 and 83 under 35 USC §103(a) as being unpatentable over Keith et al. in view of U.S. Patent No. 4,976,692 (hereinafter referred to as Atad).

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With regard to claims 57 and 58, the Applicant respectfully submits that these claims depend from independent claim 49, and thus incorporate by reference the limitations contained therein, including those which have already been shown to be absent from Keith et al. As indicated in the previous Office Action response, these limitations are also absent from Atad. Given that neither Keith et al. nor Atad disclose all of the limitations of independent claim 49, and given that claims 57 and 58 incorporate by reference these limitations, the Applicant respectfully submits that this combination of references is insufficient to establish a prima facie case of obviousness as per §2142 of the MPEP. Accordingly, the Examiner is respectfully requested to withdraw his rejection to these claims.

With regard to claims 82 and 83, the Applicant respectfully submits that these claims depend from independent claim 77, and thus incorporate by reference the limitations contained therein, including those which have already been shown to be absent from Keith et al. As indicated in the previous Office Action response, these limitations are also absent from Atad. Given that neither Keith et al. nor Atad disclose all of the limitations of independent claim 77, and given that claims 82 and 83 incorporate by reference these limitations, the Applicant respectfully submits that the combination of references cited by the Examiner is insufficient to establish a prima facie case of obviousness as per §2142 of the MPEP. Accordingly, the Examiner is respectfully requested to withdraw his rejection to these claims.

On page 5 of the Office Action, the Examiner has further rejected claims 59 and 60 under 35 USC §103(a) as being unpatentable over Keith et al. in view of U.S. Patent No. 5,636,870 (hereinafter referred to as Enhorning).

The Applicant respectfully submits that claims 59 and 60 depend from independent claim 49, and thus incorporate by reference the limitations contained therein, including those which have already been shown to be absent from Keith et al. As indicated in the previous Office Action response, these limitations are also absent from Enhorning. Given that neither Keith et al. nor Enhorning disclose all of the limitations of

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independent claim 49, and given that claims 59 and 60 incorporate by reference these limitations, the Applicant respectfully submits that the combination of references cited by the Examiner is insufficient to establish a prima facie case of obviousness as per §2142 of the MPEP. Accordingly, the Examiner is respectfully requested to withdraw his rejection to these claims.

D. Summary of New Claims 86-94

The Applicant respectfully submits that new claims 86-94 include limitations which are neither anticipated, nor rendered obvious by the references cited by the Examiner.

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III. CONCLUSION

In view of the above, it is submitted that claims 49-64 and 77-94 are in condition for allowance. Reconsideration of the rejections is requested. Allowance of claims 49-64 and 77-94 at an early date is solicited.

If the application is not considered to be in full condition for allowance, for any reason, the Applicant respectfully requests the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP 707.07(j) or in making constructive suggestions pursuant to MPEP 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,



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